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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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TITLE OF THE INVENTION (280 characters max)					
MULTI-SITE REMOTELY PRESSURIZED INJECTION SYSTEM					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	7	<input type="checkbox"/> CD(s), Number		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	2	<input checked="" type="checkbox"/> Other (specify)	ASSIGNMENT; COVER SHEET	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
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<input checked="" type="checkbox"/>	A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
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Respectfully submitted,

SIGNATURE

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Date 04/12/2004

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(if appropriate)

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MULTI-SITE REMOTELY PRESSURIZED INJECTION SYSTEM

The present invention is generally directed to the administration of a medicament and is more particularly directed to a multi-site injection system for dermal delivery of a medicament.

SUMMARY OF THE INVENTION

10 A multi-site injection system in accordance with the present invention generally includes a shell including a top and a bottom and a plurality of needles protruding from the shell bottom. Each of the needles include a lumen extending through the shell bottom.

15

A membrane is provided and disposed between the shell top and the shell bottom and an inlet is provided for introducing a fluid between the shell top and the shell bottom.

20 A diverter is also provided for selectively directing fluid between the membrane and the shell bottom and between the membrane and the shell top.

The diverter may include a manually operated valve and
25 the system may further include a supply of medicament, preferably botulinum toxin, for introduction between the membrane and the shell bottom.

An inert fluid supply may also be provided for introduction between the membrane and the shell top.

Also in accordance with the present invention, a method
5 of multi-site injection comprises providing a shell between the top and a bottom with bottom having a plurality of needles protruding therefrom with each needle including a lumen therethrough and extending through the shell bottom.

10 The method also includes providing a membrane between the shell top and the shell bottom.

More particularly, in accordance with the present invention, the method includes introducing a medicament
15 between the membrane and the shell bottom and introducing a pressurized fluid between the membrane and the shell top for forcing the medicament through the needle lumens. In this method, the medicament preferably comprises botulinum toxin.

20 BRIEF DESCRIPTION OF THE DRAWINGS

The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in
25 which:

Figure 1 is a perspective view of a multi-site injection system in accordance with the present invention generally illustrating a shell having a top and a bottom with a

plurality of needles protruding from the shell bottom. An inlet for introducing fluid between the shell top and bottom is shown along with a diverter;

5 Figure 2 is a cross sectional view of the system shown in Figure 1 more clearly illustrating the shell top, bottom and a membrane disposed between the shell top and the shell bottom along with a diverter valve for selectively directing fluid between the membrane and the shell bottom and between the
10 membrane and the shell top, Figure 2 showing a filling cycle with medication being injected into a reservoir; and

 Figure 3 is a cross sectional view similar to Figure 2 showing the diverter selectively directing fluid between the
15 membrane and top shell during an injection cycle in order to pressurize the reservoir of medicament thereby forcing the medicament through needle lumens; and

 Figure 4 is an enlarged view of the needles illustrating
20 a lumen therethrough for injection of the medicament into the stratum corneum of a users skin (not shown).

DETAILED DESCRIPTION

25 With reference to Figures 1-3, there is shown a multi-site injection system 10 in accordance with the present invention generally including a shell 12 having a top 16 and a bottom 18. A plurality of needles 22 protrude from the shell bottom 18 with each needle 22 including a lumen 24 (see Figure

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4) communicating with a reservoir 26 established by a membrane 28 disposed between the shell top 16 and the shell bottom 18.

5 It should be appreciated that the shell, membrane and needles may be made from any suitable material. Preferably, the needles have a gauge of about 28 and a length in the order of 2mm. An inlet 30 including a tube 32 and passageway 34 provide a means for introducing a fluid between the shell top 16 and shell bottom 18.

10

A diverter 38 includes a manually operated valve 40 for selectively directing fluid between the membrane 28 and shell bottom 18 into the reservoir 26.

15 As shown by the arrow 44 during a filling cycle the inlet, or supply line, introduces a medicament, preferably botulinum toxin, into the reservoir by alignment with a dip tube 48 with the passageway 34 for filling of the reservoir 26.

20

Thereafter, the diverter 38 by way of the valve 40 aligns the passageway 34 for introducing a fluid, such as saline solution, between the membrane 28 and the top shell as illustrated by the arrows 52, 54. This provides a pressure
25 above the membrane 28 which forces the medicament from the reservoir 26 through the needle lumens 24 as illustrated by the arrows 58.

Although there has been hereinabove described a specific multi-site remotely pressurized injection system in accordance with the present invention for the purpose of illustrating the manner in which the invention may be used to advantage, it
5 should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element
10 which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.

15

WHAT IS CLAIMED IS:

1. A multi-site injection system comprising:
 - a shell including a top and a bottom;
 - 5 a plurality of needles protruding from the shell bottom, each needle including a lumen extending through the shell bottom;
 - a membrane disposed between the shell top and shell bottom;
 - 10 an inlet for introducing a fluid between the shell top and the shell bottom; and
 - a diverter for selectively directing fluid between the membrane and the shell bottom and between the membrane and the shell top.
- 15 2. The system according to claim 1 wherein said diverter includes a manually operated valve.
3. The system according to claim 2 further comprising a
 - 20 supply of medicament for introduction between the membrane and the shell bottom.
4. The system according to claim 3 further comprises a
 - 25 supply of inert fluid for introduction between the membrane and the shell top.
5. The system according to claim 4 wherein said medicament comprises botulinum toxin and said inert fluid comprises a saline solution.

6. A method of multi-site injection comprises:

providing a shell including a top and a bottom, said bottom having a plurality of needles protruding therefrom with
5 each needle including a lumen therethrough and extending through the shell bottom;

providing a membrane between the shell top and the shell bottom;

introducing a medicament between the membrane and
10 the shell bottom; and

introducing a pressurized fluid between the membrane and the shell top for forcing the medicament through the needle lumen.

15 7. The method according to claim 6 wherein said medicament comprises botulinum toxin.

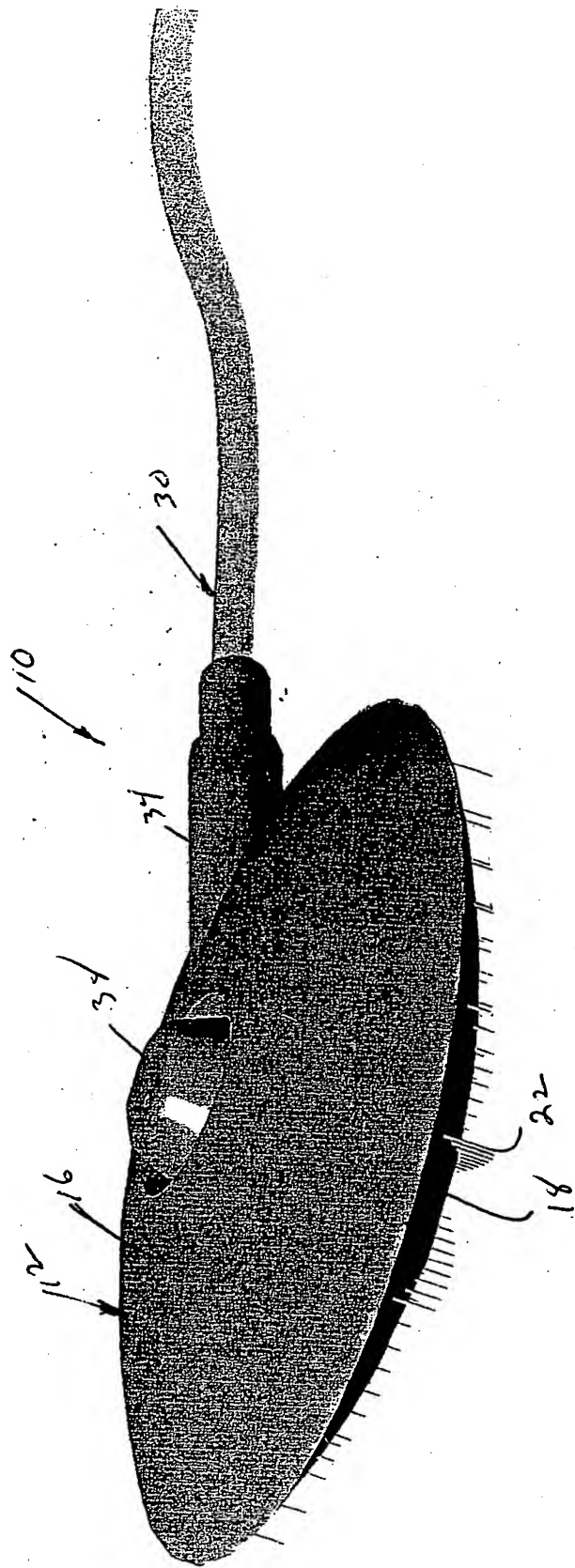
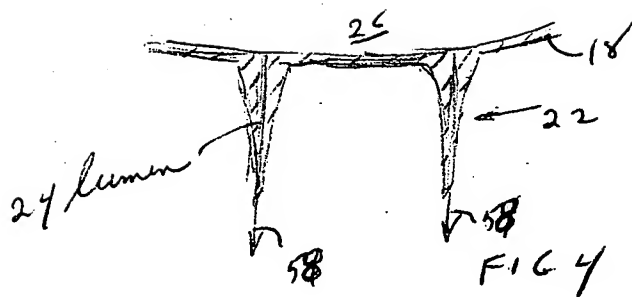
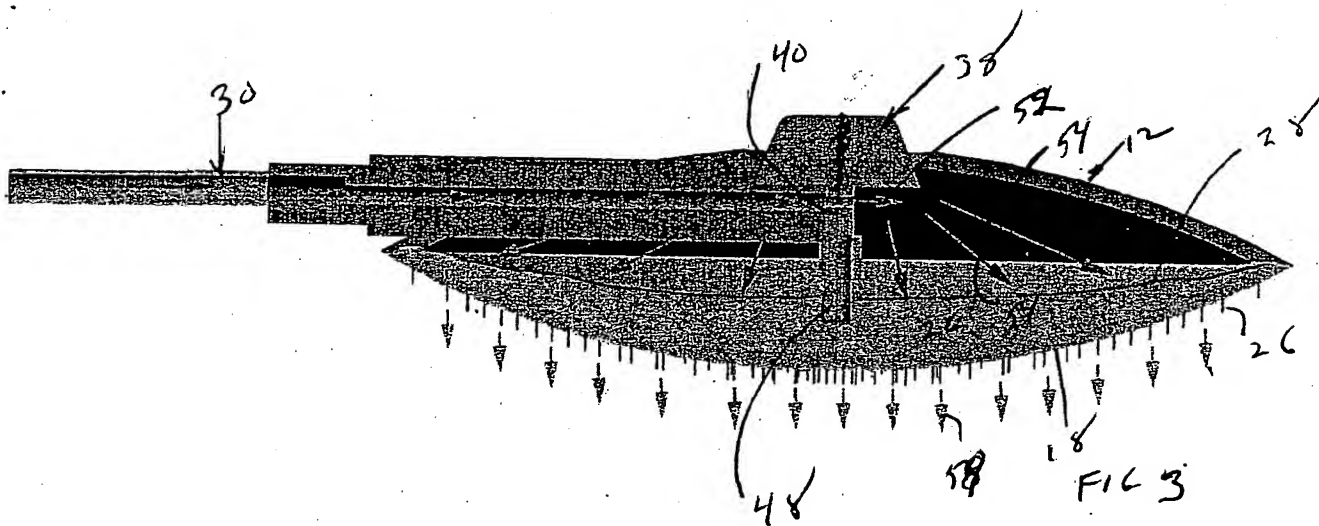
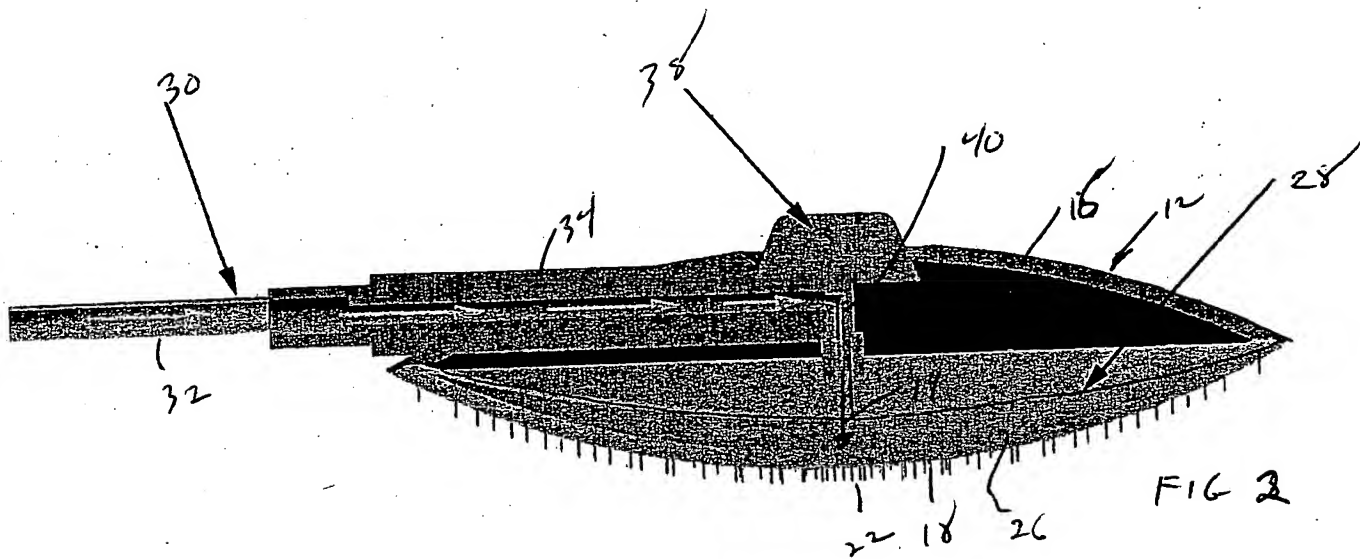


FIG. 1

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